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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/833,782	04/12/2001	D. Wade Walke	LEX-0161-USA	1934

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EXAMINER	
WALICKA, MALGORZATA A	
ART UNIT	**PAPER NUMBER**
1652	8

DATE MAILED: 01/18/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/833,782	WALKE ET AL.	
	Examiner	Art Unit	
	Malgorzata A. Walicka	1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-3 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-3 is/are rejected.

7)☒ Claim(s) 3 is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 7 .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☒ Other: *a copy of sequence search* .

The examiner acknowledges the application. Claims 1-3 are pending and are the subject of this Office action.

Detailed Office Action

1. Objections

Claim 3 is objected to under 37 CFR 1.75 as being a duplicate of claim 2 part a). When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k). It is noted that that claim 2 is written to include both limitation a) and b). Do the Applicant mean to include both limitation in the claim or they intend to write a Markush group, or to join both parts of the claim by "or"? If the both limitations are encompassed by claim 2, the scope of claim 2 and 3 are different and objection withdrawn.

2.Rejections

2.1. 35 USC section 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1-3 are rejected under 35 U.S.C. 101 because the claimed invention lacks patentable utility. The Applicants disclose novel human protein (NHP) having

amino acid sequences described by SEQ ID NO:2, encoded by DNA of SEQ ID NO:1, and assert the protein to be a novel human metalloprotease. Although the sequence analysis indicates that the claimed NHP is homologous to many metalloproteases and shares structural similarity with neurolysins, the Applicants do not describe any functional characteristics of said protein, and in fact fail to disclose any assay for NHP activity. Thus biologic role and significance of NHP are not disclosed.

Applicants assert that the NHP gene may be applied to identify its own polymorphism (page 10, line 10), to isolate a NHP gene mutant allele, page (12, line 4), and to determine the existence of a mutated form of a NHP in a person manifesting a NHP-associated phenotype, which is exemplified, on page 12 line 1, by "obesity, high blood pressure, an inflamatory disorder and **etc**. [MW]." Further, Applicant assert the NHP can be used as therapeutics in the form of NHP peptides or NHP antibodies (page 14, line 10) to directly treat diseases or disorders. However, no such diseases or disorders are mentioned. Thus, these utilities cannot be considered to be specific and substantial because Applicants do not explicitly name any particular disease or disorder, and because the specification fails to disclose any particular function or biological significance for the NHP, who are said to have a potential function based upon its amino acid sequence similarity to other known proteins. After further research, a specific and substantial, credible utility might be found for the claimed isolated compositions. This further characterization, however, is part of the act of invention and until it has been undertaken, Applicant's claimed invention is incomplete. Thus, there has been no immediately apparent or "real world" utility identified as of the filling date of the instant

application. Until an actual and specific biologic significance can be attributed to the NHP and the gene encoding it, one of ordinary skill in the art would be required to perform additional experimentation in order to determine how to use the claimed invention.

Claims 2-3 are also rejected under 35 USC § 112, the first paragraph. Since the claimed invention is not supported by either a specific or substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art would not know how to use the claimed invention, so that it would operate as intended, without undue experimentation.

2. 2. 35 U.S.C. 112, second paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 2 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 2 is rejected because the phrase "stringent conditions" is indefinite. The examiner acknowledges exemplifying highly stringent conditions on page 4 line, 14 of the application. However, it is unclear whether the term "stringent conditions" has the same meaning as "highly stringent conditions." Besides, the stringent conditions are merely exemplified and there is a suggestion that other hybridization conditions are intended to be included; see page 4, line 23 and page 5, line 7. In the art what

conditions are considered "stringent" varies widely depending on the situation and person making the determination. Therefore, it is unclear how homologous to a sequence identified by SEQ ID NO:1 a sequence must be to be within the scope of the claim. Specifying the hybridization conditions in the claims will lead to vacating this rejection.

2.3. 35 U.S.C. 112, first paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2.3.1. Lack of written description

Claim 1 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The claim is directed to an isolated nucleic acid molecule comprising at least 24 contiguous bases of the nucleotide sequence disclosed in SEQ ID NO:1. The genus of claimed nucleic acid molecules is a large variable genus, because there is an extremely large number of the at least 24 contiguous base fragments in SEQ ID NO:1 and the number of species of DNA that may contain any of the at least 24 contiguous bases of the nucleotide sequence disclosed in SEQ ID NO:1 is even greater. The specification fails to describe any of

representive species of the claimed genus by any identifying characteristics or properties other than containing 24 contiguous base fragments of SEQ ID NO:1. Also, neither special functional or structure features of said DNA molecules are disclosed. In view of lack of any functional and structural characteristics of the claimed DNA molecules, Applicants failed to sufficiently describe the claimed invention in such full, clear, concise, and exact terms that a skilled artisan would recognize they were in possession of the claimed invention.

2. 3.2. Lack of enablement

Claim 1 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Due to the lack of written description, see the above rejection, no one skilled in the art is able to construct the claimed DNA molecule comprising any of 24 contiguous base fragment of SEQ ID :1. Therefore, undue experimentation is necessary to make the claimed invention. Factors to be considered in determining whether undue experimentation is required, are summarized *In re* Wands [858 F.2d 731, 8 USPQ 2nd 1400 (Fed. Cir. 1988)]. The Wands factors are: (a) the nature of the invention, (b) the breadth of the claim, (c) the state of the prior art, (d) the relative skill of those in the art, (e) the predictability of the art, (f) the presence or absence of working example, (g) the amount of direction or guidance presented, (h) the quantity of experimentation necessary.

The nature and breath of the claimed invention encompasses any DNA molecule comprising any fragments of at least 24 bases of SEQ ID NO:1. While methods of gene manipulation are well known in the relevant art, and skills of the artisans highly developed, isolating any 24 base fragment of SEQ ID NO:1 and inserting it into any other sequence is outside the realm of routine experimentation. The probability of success in obtaining the claimed invention is very low.

The disclosure does not provide a single example of the claimed invention. The attributes and features of the claimed DNA molecule, other than containing an at least 24 base fragment of SEQ ID NO:1, are not disclosed. Applicants did not provide any guidance as to which of the at least 24 base fragment of SEQ ID NO:1 to use for insertion and to which DNA sequence so as to make the claimed invention. Thus, without the further guidance on the part of Applicants as to which fragment of SEQ ID NO:1 to chose and without identification of DNA sequence that will be used to insert said fragment, and in which position, experimentation left to those in the art is improperly extensive and undue.

2.4. 35 USC section 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless - (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 3 is rejected under 35 U.S.C. 102(b) as being anticipated by Kato A. et al (Targeting of endopeptidase 16.4 24.16 to different subcellular compartments by alternative promoter usage, J. Biol. Chem. 1997, 272, 15313-15322).

The claim is directed to an isolated DNA molecule comprising at least 24 contiguous bases of nucleotide sequence disclosed in SEQ ID NO:1.

Kato et al disclose endopeptidase 16.4 whose sequence comprises many at least 24 contiguous base fragments of SEQ ID NO:1 of the instant application; see the enclosed result of sequence search.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Malgorzata A. Walicka, Ph.D., whose telephone number is (703) 305-7270. The examiner can normally be reached Monday-Friday from 10:00 a.m. to 4:30 p.m.

If attempts to reach examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura Achutamurthy, Ph.D. can be reached on (703) 308-3804. The fax phone number for this Group is (703) 305-3014.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionists whose telephone number is (703) 308-0196.

Malgorzata A. Walicka, Ph.D.

Art Unit 1652

Assistant Patent Examiner

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